

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jill A. Jacobson on October 15, 2004.

2. The application has been amended as follows:

The claims have been amended as follows:

Claim 1 (previously presented): An isolated monoclonal anti-idiotypic antibody 11D10 produced by hybridoma cell line ATCC No. HB 12020.

Claim 2 (currently amended): ~~The~~ A labeled antibody comprising the antibody of claim 1, ~~further comprising a~~ wherein said label is capable of producing a detectable signal.

¹⁴
Claim ~~3~~ (previously presented): A hybridoma cell line designated ATCC No. HB 12020.

¹⁶
Claim ~~4~~ (previously presented): A purified antibody having all the identifying characteristics of antibody produced by a hybridoma cell line according to claim ~~3~~.¹⁴

¹⁵
Claim ~~5~~ (original): A hybridoma having all the identifying characteristics of a cell of the hybridoma cell line according to claim ~~3~~.¹⁴

Claims 6-19 (canceled)

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²³
Claim ~~20~~ (currently amended): A polypeptide having immunological activity of anti-idiotypic antibody 11D10, wherein the polypeptide comprises an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of anti-idiotypic antibody 11D10, and an immunoglobulin variable region containing three heavy chain CDRs of anti-idiotypic antibody 11D10, wherein anti-idiotypic antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020 ~~wherein the light chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020, and wherein the heavy chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020, and wherein the immunological activity of the polypeptide is an ability to stimulate a specific immune response against human milk fat globule (HMFG).~~

Claims 21-22 (canceled)

²⁴
Claim ~~23~~ (previously presented): The polypeptide of claim ²³~~20~~, wherein the light chain variable region amino acid sequence is contained in SEQ ID NO:2 and the heavy chain variable region amino acid sequence is contained in SEQ ID NO:4.

Claims 24-25 (canceled)

²⁵
Claim ~~26~~ (previously presented): The polypeptide of claim ²³~~20~~, wherein the polypeptide contains a sequence of at least 2 contiguous amino acids which are identical in forward or reverse orientation to 2 contiguous amino acids of a sequence in human mucin from human milk fat globule (HMFG), wherein said HMFG sequence is contained in SEQ ID NO:33.

³⁵
Claim ~~27~~ (original): A fusion polypeptide comprising the polypeptide of claim ²³~~20~~.

³⁷
Claim ~~28~~ (previously presented): The fusion polypeptide of claim ³⁵~~27~~ further comprising a cytokine.

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Claim ³⁸~~29~~ (previously presented): The fusion polypeptide of claim ³⁷~~28~~, wherein the cytokine is granulocyte macrophage colony stimulating factor.

Claim ³⁹~~30~~ (previously presented): The fusion polypeptide of claim ³⁷~~28~~, wherein the cytokine is interleukin 2.

Claim 31 (canceled)

Claim ⁴⁰~~32~~ (currently amended): The fusion polypeptide of claim ³⁵~~27~~, wherein the immunoglobulin variable region of the polypeptide of claim ²³~~20~~, containing three CDRs from the light chain variable region of anti-idiotypic antibody 11D10, and the immunoglobulin variable region of the polypeptide of claim ²³~~20~~, containing three CDRs from the heavy chain variable region of anti-idiotypic antibody 11D10, are linked by a linker polypeptide of about 5 to 20 amino acids.

Claim ⁴²~~33~~ (previously presented): The fusion polypeptide of claim ³⁵~~27~~, comprising the light chain variable region and the heavy chain variable region of anti-idiotypic antibody 11D10, wherein the light chain variable region and the heavy chain variable region are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim ⁴⁴~~34~~ (previously presented): The fusion polypeptide of claim ³⁵~~27~~ further comprising a heterologous immunoglobulin constant region.

Claim ⁴⁶~~35~~ (currently amended): A humanized antibody comprising three CDRs from the light chain variable region of antibody 11D10, three CDRs from the heavy chain variable region of antibody 11D10, and a constant region that is a human sequence, wherein antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020, and wherein the humanized antibody is able to stimulate a specific immune response against human milk fat globule (HMFG), wherein the light chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC No. HB 12020, and wherein the heavy chain variable region

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~~amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC No. HB 12020.~~

²⁶
Claim ~~36~~²³ (original): A polymeric 11D10 polypeptide comprising a plurality of the polypeptide of claim ~~20~~.

³
Claim ~~37~~ (currently amended): A composition comprising the anti-idiotypic antibody ~~11D10~~ of claim 1 and a pharmaceutically acceptable excipient.

Claim 38 (canceled)

⁵⁵
Claim ~~39~~ (currently amended): A composition comprising a pharmaceutically acceptable excipient and a polypeptide having immunological activity of anti-idiotypic antibody 11D10, wherein the polypeptide comprises an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of anti-idiotypic antibody 11D10, and an immunoglobulin variable region containing three heavy chain CDRs of anti-idiotypic antibody 11D10, wherein anti-idiotypic antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020 ~~wherein the light chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020, and wherein the heavy chain variable region amino acid sequence is contained in an antibody produced by a hybridoma cell line designated ATCC NO. HB 12020, and wherein the immunological activity of the polypeptide is an ability to stimulate a specific immune response against human milk fat globule (HMFG).~~

⁷
Claim ~~40~~ (currently amended): An immunogenic composition comprising the anti-idiotypic antibody ~~11D10~~ of claim 1 and a pharmaceutically acceptable excipient.

Claim 41 (canceled)

³³
Claim ~~42~~²³ (previously presented): An immunogenic composition comprising the polypeptide of claim ~~20~~ and a pharmaceutically acceptable excipient.

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Claim ~~43~~⁸ (previously presented): The immunogenic composition of claim ~~40~~⁷, further comprising an adjuvant.

Claims 44-45 (canceled)

Claim ~~46~~¹⁰ (currently amended): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of ~~monoclonal~~ the anti-idiotypic antibody 11D10 of claim 1 to the individual.

Claim ~~47~~⁹ (currently amended): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of the vaccine immunogenic composition of claim ~~43~~⁸ to the individual.

Claim ~~48~~¹¹ (original): The method of claim ~~46~~¹⁰, wherein the advanced human milk fat globule associated disease is breast cancer.

Claim ~~49~~⁴ (currently amended): A method for ~~removing~~ promoting clearance of a labeled anti-human milk fat globule (HMFG) antibody that binds to the antibody of claim 1 from the circulation or tissues of an individual who has received [[a]] the labeled anti-HMFG antibody, comprising administering ~~monoclonal~~ the antibody 11D10 of claim 1 to the individual.

Claim 50 (canceled)

Claim ~~51~~⁵ (currently amended): A method for detecting an anti-human milk fat globule immunological response in an individual comprising the steps of (a) contacting a biological sample from the individual with the monoclonal anti-idiotypic antibody 11D10 of claim 1 under conditions that permit formation of a stable complex between the monoclonal anti-idiotypic antibody 11D10 and an antibody containing the paratope of the monoclonal anti-idiotypic antibody 11D10; and (b) detecting any of the stable complexes

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formed, wherein the presence of the complexes is indicative of the presence of an anti-human milk fat globule immunological response in the individual.

Claims 52-53 (canceled)

Claim ¹²~~54~~ (currently amended): A kit comprising the anti-idiotypic antibody 44D40 of claim 1 in suitable packaging.

Claim ¹³~~55~~ (currently amended): The kit of claim ¹²~~54~~, wherein the antibody 44D40 comprises a detectable label.

Claim ²⁷~~56~~ (previously presented): A kit comprising the polypeptide of claim ²³~~20~~ in suitable packaging.

Claims 57-58 (canceled)

Claim ⁶~~59~~ (currently amended): A composition comprising an effective amount of the anti-idiotypic antibody of claim 1, wherein an effective amount is an amount sufficient to elicit an anti-human milk fat globule immune response.

Claim ¹⁷~~60~~ (previously presented): A composition comprising an effective amount of the antibody of claim ¹⁶~~4~~, wherein an effective amount is an amount sufficient to elicit an anti-human milk fat globule immune response.

Claim ²⁸~~61~~ (previously presented): A composition comprising an effective amount of the polypeptide of claim ²³~~20~~, wherein an effective amount is an amount sufficient to elicit an anti-human milk fat globule immune response.

Claim ⁵⁶~~62~~ (previously presented): The composition of claim ⁵⁵~~39~~, wherein the specific immune response comprises production of HMFG-specific antibody.

Claim ⁵⁷~~63~~ (previously presented): The composition of claim ⁵⁵~~39~~, wherein the specific immune response comprises production of HMFG-specific T cells.

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⁴⁷
Claim ~~64~~ (previously presented): The humanized antibody of claim ~~35~~⁴⁶, wherein the specific immune response comprises production of HMFG-specific antibody.

⁴⁸
Claim ~~65~~ (previously presented): The humanized antibody of claim ~~35~~⁴⁶, wherein the specific immune response comprises production of HMFG-specific T cells.

Claim 66 (canceled)

⁴⁵
Claim ~~67~~ (previously presented): The fusion polypeptide of claim ~~34~~⁴⁴, wherein the immunoglobulin constant region is human.

³⁴
Claim ~~68~~ (previously presented): The immunogenic composition of claim ~~42~~³³, further comprising an adjuvant.

¹⁸
Claim ~~69~~ (previously presented): The purified antibody of claim ~~4~~¹⁶, said antibody comprising the sequence of SEQ ID NO:2.

¹⁹
Claim ~~70~~ (previously presented): The purified antibody of claim ~~4~~¹⁶, said antibody comprising the sequence of SEQ ID NO:4.

⁴³
Claim ~~71~~ (currently amended): The fusion polypeptide of claim ~~33~~⁴², wherein the light chain variable region and the heavy chain variable region of ~~antibody 11D10~~ are joined by a linker polypeptide of about 5 to 20 amino acids.

⁴⁹
Claim ~~72~~ (previously presented): The humanized antibody of claim ~~35~~⁴⁶, wherein the framework regions are human sequences.

⁵⁸
Claim ~~73~~ (currently amended): A humanized antibody comprising three CDRs from the light chain variable region of antibody 11D10, three CDRs from the heavy chain variable region of antibody 11D10, and framework regions that are human sequences, wherein antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020, and wherein the humanized antibody is able to stimulate a specific immune response against human milk fat globule (HMFG).

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Claim ²⁰~~74~~ (previously presented): A composition comprising the purified antibody of claim ¹⁶~~74~~ and a pharmaceutically acceptable excipient.

Claim ²¹~~75~~ (previously presented): A composition according to claim ²⁰~~74~~, wherein the composition is immunogenic.

Claim ²²~~76~~ (previously presented): A composition according to claim ²¹~~75~~, further comprising an adjuvant.

Claim 77 (canceled)

Claim ³⁶~~78~~ (previously presented): A fusion polypeptide according to claim ³⁵~~27~~, wherein the amino acid sequences of the light chain variable region and the heavy chain variable region are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively:

Claim ⁴¹~~79~~ (previously presented): A fusion polypeptide according to claim ⁴⁰~~32~~, wherein the linker polypeptide comprises the amino acid sequence (GGGS)₃ (SEQ ID NO:35).

Claim ⁵⁰~~80~~ (previously presented): A humanized antibody according to claim ⁴⁶~~35~~, wherein the light chain variable region of antibody 11D10 and the heavy chain variable region of antibody 11D10 are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim ⁵¹~~81~~ (previously presented): A composition comprising the humanized antibody of claim ⁴⁶~~35~~ and a pharmaceutically acceptable excipient.

Claim ⁵³~~82~~ (previously presented): A composition according to claim ⁵¹~~81~~, wherein the composition is immunogenic.

Claim ⁵⁴~~83~~ (previously presented): A composition according to claim ⁵³~~82~~ further comprising an adjuvant.

Claim ⁶⁰~~84~~ (currently amended): A humanized antibody comprising three CDRs from the light chain variable region of antibody 11D10, three CDRs from the heavy chain variable region of antibody 11D10, and framework regions that are human sequences, wherein

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antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB 12020, wherein the humanized antibody is able to stimulate a specific immune response against human milk fat globule (HMFG), and wherein the light chain variable region of antibody 11D10 and the heavy chain variable region of antibody 11D10 are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

⁶²
Claim ~~85~~ (previously presented): A composition comprising the humanized antibody of claim ~~84~~ and a pharmaceutically acceptable excipient.

⁶³
Claim ~~86~~ (previously presented): A composition according to claim ~~85~~, wherein the composition is immunogenic.

⁶⁴
Claim ~~87~~ (previously presented): A composition according to claim ~~86~~, further comprising an adjuvant.

⁶⁵
Claim ~~88~~ (previously presented): An antibody comprising a light chain variable region amino acid sequence contained in SEQ ID NO:2 and a heavy chain variable region amino acid sequence contained in SEQ ID NO:4, wherein the antibody is able to stimulate a specific immune response against human milk fat globule (HMFG).

⁶⁶
Claim ~~89~~ (previously presented): A composition comprising the antibody of claim ~~88~~ and a pharmaceutically acceptable excipient.

⁶⁷
Claim ~~90~~ (previously presented): A composition according to claim ~~89~~, wherein the composition is immunogenic.

⁶⁸
Claim ~~91~~ (previously presented): A composition according to claim ~~90~~, further comprising an adjuvant.

⁶⁹
Claim ~~92~~ (currently amended): An isolated antibody comprising three CDRs from the light chain variable region of anti-idiotypic antibody 11D10 and three CDRs from the heavy chain variable region of anti-idiotypic antibody 11D10, wherein anti-idiotypic antibody 11D10 is produced by the hybridoma cell line designated ATCC No. HB

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12020, wherein the CDRs from the light chain variable region are contained in SEQ ID NO:2 and the CDRs from the heavy chain variable region are contained in SEQ ID NO:4, and wherein the antibody is able to stimulate a specific immune response against human milk fat globule (HMFG).

⁷¹
Claim ~~93~~ (previously presented): A composition comprising the antibody of claim ⁶⁹~~92~~ and a pharmaceutically acceptable excipient.

⁷²
Claim ~~94~~ (previously presented): A composition according to claim ⁷¹~~93~~, wherein the composition is immunogenic.

⁷³
Claim ~~95~~ (previously presented): A composition according to claim ⁷²~~94~~, further comprising an adjuvant.

²⁹
Claim ~~96~~ (previously presented): A composition comprising the polypeptide of claim ²³~~95~~ and a pharmaceutically acceptable excipient.

Claim 97 (canceled)

⁷⁴
Claim ~~98~~ (previously presented): A polypeptide comprising an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of antibody 11D10, or an immunoglobulin variable region containing three heavy chain CDRs of antibody 11D10, wherein antibody 11D10 is produced by a hybridoma cell line designated ATCC NO. HB 12020.

⁷⁵
Claim ~~99~~ (previously presented): A composition comprising the polypeptide of claim ⁷⁴~~98~~ and a pharmaceutically acceptable excipient.

⁷⁶
Claim ~~100~~ (previously presented): A polypeptide according to claim ⁷⁴~~98~~, comprising an immunoglobulin variable region containing the three light chain CDRs of antibody 11D10.

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Claim ⁷⁷~~101~~ (previously presented): A polypeptide according to claim ⁷⁴~~98~~, comprising an immunoglobulin variable region containing the three heavy chain CDRs of antibody 11D10.

Claim ⁷⁸~~102~~ (previously presented): A polypeptide according to claim ⁷⁴~~98~~, wherein the light chain variable region is contained in SEQ ID NO:2.

Claim ⁷⁹~~103~~ (previously presented): A polypeptide according to claim ⁷⁴~~98~~, wherein the heavy chain variable region is contained in SEQ ID NO:4.

Claim ⁸⁰~~104~~ (previously presented): A polypeptide comprising an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of antibody 11D10 and an immunoglobulin variable region containing three heavy chain CDRs of antibody 11D10, wherein antibody 11D10 is produced by a hybridoma cell line designated ATCC NO. HB 12020, and wherein the light and heavy chain variable region sequences are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively, and wherein the antibody is able to stimulate a specific immune response against human milk fat globule (HMFG).

Claim ⁵⁷~~105~~ (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of an antibody according to claim ⁴⁶~~35~~ to the individual.

Claim ⁵⁹~~106~~ (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of an antibody according to claim ⁵⁸~~73~~ to the individual.

Claim ⁶¹~~107~~ (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step

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of administering an effective amount of an antibody according to claim ⁶⁰~~84~~ to the individual.

Claim ⁷⁰~~108~~ (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of an antibody according to claim ⁶⁹~~92~~ to the individual.

Claim ³⁰~~109~~ (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of a polypeptide according to claim ²³~~20~~ to the individual.

Claim ^{8/10}~~110~~ (previously presented): A method of eliciting an immune response in an individual with advanced human milk fat globule associated disease comprising the step of administering an effective amount of a polypeptide according to claim ⁸⁰~~104~~ to the individual.

Claims 111-124 (canceled)

Claim ³¹~~125~~ (new): The polypeptide of claim ²³~~20~~, wherein the specific immune response comprises production of HMFG-specific antibodies.

Claim ³²~~126~~ (new): The polypeptide of claim ²³~~20~~, wherein the specific immune response comprises production of HMFG-specific T cells.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.